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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Selamectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Pfizer, Inc. The NADA provides for veterinary prescription use of selamectin solution as a topical parasiticide for dogs and cats.

EFFECTIVE DATE: (*Insert date of publication in the* **Federal Register**.)

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed NADA 141–152 that provides for topical veterinary prescription use of Revolution™ (selamectin) solution. Selamectin kills adult fleas and prevents flea eggs from hatching for 1 month, and it is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and treatment and control of ear mite (*Otodectes cynotis*) infestations in dogs and cats; in dogs for treatment and control of sarcoptic mange (*Sarcoptes scabiei*); and in cats for treatment of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections. The NADA is approved as of May 26, 1999, and the regulations are amended by adding 21 CFR 524.2098 to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning May 26, 1999, because no active ingredient (including any ester or salt of the drug) has been previously approved in any other application filed under section 512(b)(1) of the act.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 524

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 524.2098 is added to read as follows:

§ 524.2098 Selamectin.

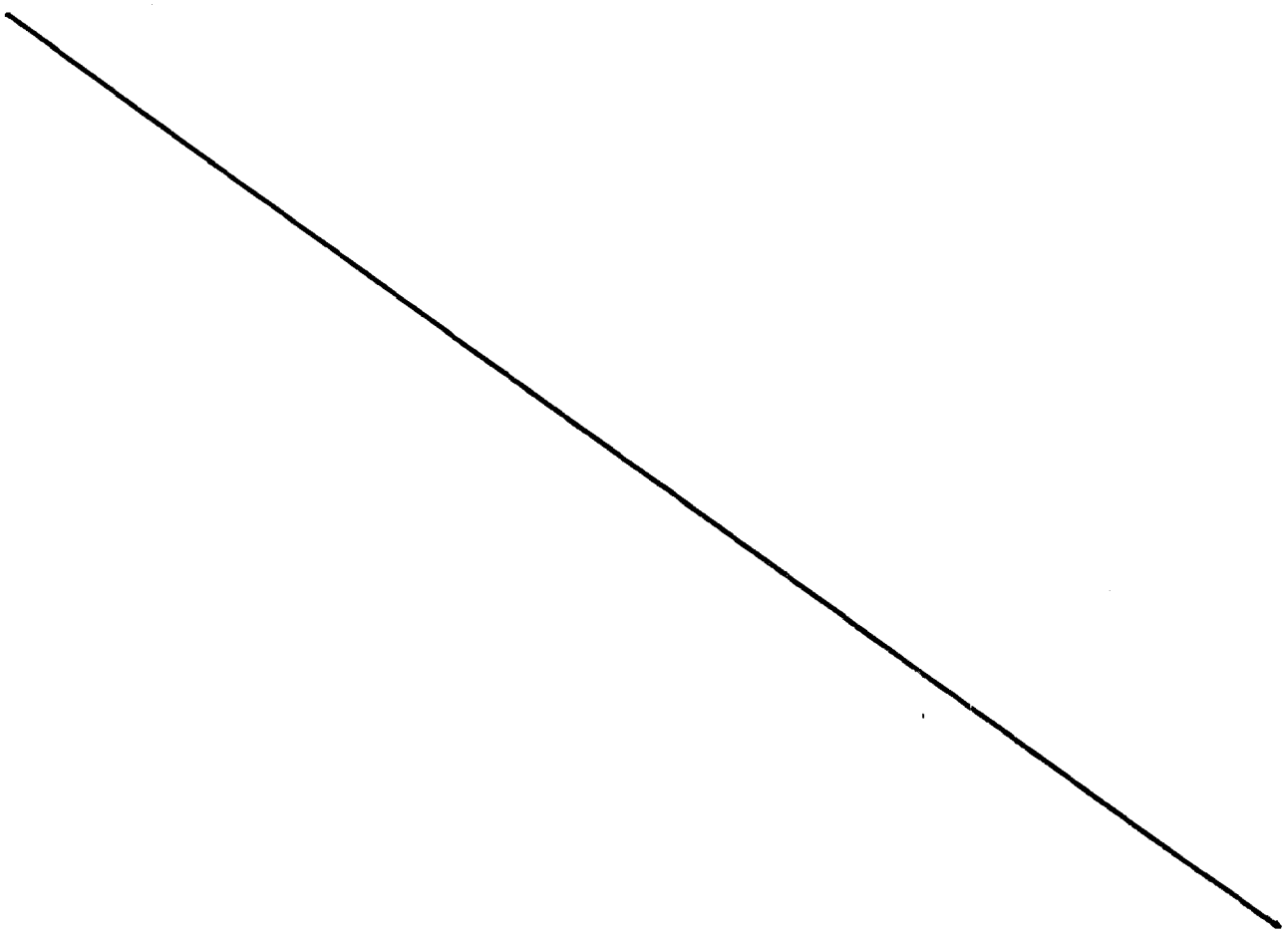
(a) *Specifications.* Each milliliter contains 60 or 120 milligrams of selamectin.

(b) *Sponsor.* See 000069 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*—(1) *Amount.* 2.7 milligrams of selamectin, topically, per pound (6 milligrams per kilogram) of body weight once a month.

(2) *Indications for use.* Kills adult fleas and prevents flea eggs from hatching for 1 month, and it is indicated for the prevention and control of flea infestations (*Ctenocephalides felis*), prevention of heartworm disease caused by *Dirofilaria immitis*, and treatment and control of ear mite (*Otodectes cynotis*) infestations in dogs and cats. Treatment and control of sarcoptic mange (*Sarcoptes scabiei*) in dogs. Treatment of intestinal hookworm (*Ancylostoma tubaeforme*) and roundworm (*Toxocara cati*) infections in cats. For dogs and cats 6 weeks of age and older.



(3) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 29 Jun 99
June 29, 1999

George A. Mitchell
Acting Director, Center for Veterinary Medicine

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

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